US Generics Market

Healthy revenue growth for Indian pharma companies in FY2024; regulatory risks persist

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Agenda

ICRA

1 Overview of US pharmaceutical market

2 Performance of Indian pharma companies in the US generics market

3 Key growth drivers for Indian pharma companies in the US market

4 Key challenges in the US generics market

5 Regulatory environment

6 ICRA's rating distribution

Highlights

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ICRA expects healthy revenue growth of 11-13% from the US market for its sample set companies in FY2024, backed by new product launches, reduced pricing pressures in addition to faster abbreviated new drug application (ANDA) approvals and some product shortages.

However, with increased regulatory risks, its impact on future earnings of sample set companies remains a key monitorable.

The US continues to be the largest pharmaceutical market in the world, accounting for around 45% of the global pharmaceutical industry by value. The US has always been a key market for most leading Indian pharmaceutical companies as well, accounting for a sizeable share of their revenues.

However, owing to consistent pricing pressures, lack of major blockbuster products going off-patent and increased regulatory scrutiny in recent years, the share of revenues from the US market for Indian pharmaceutical companies declined to ~35% in FY2022 vis-à-vis 40% in FY2020. However, with easing of pricing pressures, significant new launches and shortages for some molecules, this proportion increased to 37% in FY2023 and 38% in H1 FY2024.

Revenue growth from the US market for ICRA's sample set companies was healthy at 16% YoY in FY2023 and increased further to 25% YoY in H1 FY2024. While the momentum is likely to sustain, ICRA expects the sample set's revenues to grow by 11-13% in FY2024 due to the high base of H2 FY2023.

Apart from some key drugs going off-patent, product shortages in select segments in recent quarters have also been a growth driver for generic companies in the US market to some extent.

With increased regulatory scrutiny, the incidences of warning letters and import alerts have increased and remains a key credit risk. This has led to delays in product launches translating into failure to supply penalties and entailing significant costs burden towards remedial measures including hiring consultants and consuming additional management bandwidth, in turn impacting profit margins.

Indian pharma companies have taken a host of initiatives to combat various US market-related risks. These include, increased focus on complex therapies, and optimising R&D budgets, exploring inorganic opportunities in branded segment, cutting down on unviable ANDAs and dual filling for ANDAs.

^Cumulated for thirteen companies

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Thank You!